

## **REMARKS**

### **I. Introduction**

Claims 38 – 43 are currently pending and are rejected.

### **II. 35 USC § 102(b) rejection**

Claim 38 is rejected under 35 USC 102(b) as being anticipated by Wakayama (Derwent 2001-57445 or JP 2001163772A). The Examiner finds Wakayama teaches a method of administering to a human an effective amount of lycopene, and when Wakayama's lycopene is administered, it would intrinsically have the same underlining claimed functional effect as presently claimed.

Applicants respectfully traverse the rejection and request it be withdrawn.

Applicants are providing a full translation of Wakayama. The animal model used by Wakayama is for senile cataracts. Applicants submit the population of individuals which would have received lycopene treatment for senile cataracts is not co-extensive with the population which would be at risk for polycystic ovary syndrome, as the population at risk for polycystic ovary syndrome is of substantially younger women, i.e., of reproductive age.

For example, see Tan et al., Comparison of age-specific cataract prevalence in two population based surveys 6 years apart, BMC OPHTHALMOLOGY, 6:17 (2006) (copy provided with Information Disclosure Statement), indicating the incidence of cataracts in an aging population of greater than 50 years. See also, Khan, Polycystic Ovarian Syndrome, <http://emedicine.medscape.com/article/256806-overview> (updated September 4, 2009) (copy provided with Information Disclosure Statement), indicating polycystic ovarian syndrome is most frequent in women in the reproductive age.

As Wakayama fails to teach or suggest all of the limitations of claim 38, Applicants request the rejection be withdrawn.

### **III. 35 USC § 103(a) rejection**

Claims 38 - 43 are rejected under 35 USC 103(a) as being unpatentable over Lorant et al. (US 6,623,769) in view of Murad (US 5,962,517) and de Salvert (US 5,827,520).

The Examiner finds Lorant et al. teaches an effective amount of lycopene is administered to treat acne. The Examiner finds Applicants admit that acne is a disorder associated with

androgen signaling. Therefore, when the use of Lorant's lycopene is administered in effective amounts to the claimed human subjects body to treat acne, Lorant's lycopene would intrinsically have the same underlying claimed functional effect as the claimed invention. However, Lorant does not disclose the combination of lycopene and vitamins E and C administered to a subject in need thereof to treat pathologies associated with androgen signaling. The Examiner finds Murad teaches vitamin E treats disorders associated with androgen signaling such as acne, and de Salvert teaches vitamin C treats pathologies associated with androgen signaling such as acne. Thus, according to the Examiner, it would have been obvious to one of skill in the art to modify the teachings of Lorant to include vitamin E and C as taught by Murad and de Salvert to practice the claimed invention. Applicants respectfully traverse the rejection, and request it be withdrawn.

Applicants submit it is improper to equate acne (which may or may not occur in polycystic ovary syndrome) and polycystic ovary syndrome itself. It is well known there are many causes of acne, and the population of people who suffer from acne is certainly not co-extensive the population of people who suffer from polycystic ovary syndrome. For example, males may suffer from acne. Not all women with acne have polycystic ovary syndrome and not all women with polycystic ovary syndrome have acne.

With this proviso in mind, the references, all of which are related to treating acne, do not teach or suggest the use of lycopene for treating polycystic ovary syndrome. For example, Lorant teaches use of lycopene as suitable for treatment of the scalp and/or of acne, as it inhibits the activity of metalloproteinases, especially type 1 metalloproteinases. There is no teaching or suggestion that this activity would be of interest in treating an individual at risk for polycystic ovary syndrome. Similarly, the vitamin complex of Murad is of no help, as again, there is no teaching or suggestion that this can be of use in administering to someone at risk for polycystic ovary syndrome. Likewise, de Salver teaches a topical polyol treatment for acne, and does not address the deficiencies of Lorant and/or Murad.

The Examiner argues "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose...."<sup>1</sup> However, the

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<sup>1</sup> Although the Examiner cited § 2114.06, Applicants believe the Examiner intended to cite § 2144.06, and request clarification if they are in error.

provisions of MPEP § 2144.06 are inapposite to the present claims. None of the references teach or suggest lycopene, vitamin E and vitamin C are equivalents, or may be substituted for one another to achieve a common effect. There is no teaching or suggestion in any of the art that vitamins C or E may be substituted for the lycopene of Lorant in order to treat acne, or the lycopene of Lorant may be used in place of vitamins E or Murad or vitamin C of de Salvert, especially since de Salvert is disclosed to be applied topically.

Mere identification in the prior art of each component of a composition does not show that the combination as a whole lacks the necessary attributes for patentability, i.e., is obvious. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). To establish a prima facie case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention. *Eli Lilly and Co. v. Zenith Goldline Pharma., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006). In the present case, none of the references teach or suggest incidence risk reduction of polycystic ovary syndrome by the administration of lycopene. Murad utilizes a vitamin E source in combination with a host of other ingredients, and provides no disclosure vitamin E by itself is suitable for treating acne, or for incidence risk reduction of polycystic ovary syndrome associated with androgen signaling. Similarly, de Salvert also fails to disclose vitamin C by itself is suitable by itself for treating acne, or for incidence risk reduction of polycystic ovary syndrome associated with androgen signaling.

As the rejection under 35 USC 103(a) is improper, Applicants request it be withdrawn.

#### **IV. Summary**

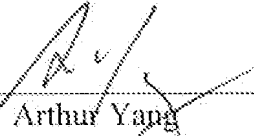
Applicants have made a *bona fide* attempt to address all matters raised by the Examiner. Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued. If any remaining matters need to be resolved, Applicants respectfully request an interview with the Examiner prior to any official action being taken by the Office in response to these arguments and amendments in order to facilitate allowance of the pending claims.

It is believed fees, other than the fee associated with the filing of an Information Disclosure Statement, are presently required. If a fee is required, please charge the same to Deposit Account 50-4255.

Respectfully submitted,

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By



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